SEP 3 0 2011

510(k) Summary of Safety and Effectiveness

K111019

Contact Information

Submitter's Address:

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Contact Person

Virginie Lafage, PhD
Vice President and Chief Technology Officer:

Date

February 14, 2011

Device Name and Classification

Tradename	Surgimap Spine
Common Name:	Picture Archiving and Communication System (PACS)
Section:	892.2050
Class	II
Product Code:	LLZ

Predicate Device

Tradename	TraumaCad 2.0
510(k) number:	K073714
Common Name:	Picture Archiving and Communication System (PACS)
Section:	892.2050
Class	II
Product Code:	LLZ

Device description

Surgimap Spine is a software solution developed for the medical community. It is intended to be used to view, store, and transport images as well as perform spine related measurements and plan surgical procedures. The image formats supported encompass the standard image formats (jpeg, tiff, png, ...) and also the DICOM images. Images can be stored in a database and measurements (generic or spine specific) can be overlaid to each image. Surgimap Spine also offers the ability for the end user to plan certain surgical procedures such as osteotomies of the spine and templating generic implants (screws and interbody cages). SurgiSmap Spine is a standalone application developed for windows environment. Surgimap Spine can be downloaded directly from www.surgimap.com via the Internet and run off a digital storage such as USB or personal computer hard drive

Intended Use

The Surgimap Spine software is intended for assisting healthcare professionals in viewing, storing, measuring images as well as planning orthopedic surgeries. The device allows service providers to perform generic as well as spine related measurements on images, to plan surgical procedures (osteotomies), and includes tools for measuring anatomical components for placements of surgical implants. Clinical judgment and experience are required to properly use the software.

Comparison of Technological Characteristics

The tabulated comparison of technological characteristics between Surgimap Spine and its predicated device is outlined in the table hereafter:

Feature	TraumaCad 2.0	Surgimap Spine
Computer	PC Compatible	Same
Operating System	Windows	Same
Image Input	Can receive digital images from various sources	Same
Number of images that can be simultaneously viewed on the screen	Four	Four
Runs on Server	Yes	No
Trauma Module	Yes	No
Osteotomy Module	Yes	Yes

Pre-operative planning	Allowed	Same
Patient Contact	None	Same
Control of life-saving devices	None	Same
Human Intervention for interpretation and manipulation of images	Required	Same
Ability to add additional Modules when available	Yes	Yes
Database	Yes	Yes
Measurements	Yes	Yes
Templating	Yes	Yes (partial)
Web Content	unknown	Yes

Performance data

Not Applicable

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Nemaris, Inc.
% Mr. Keith Barritt
Attorney
Fish & Richardson P.C.
1425 K Street, N.W., Suite 1100
WASHINGTON DC 20005

SEP 30 2011

Re: K111019
Trade/Device Name: Surgimap Spine
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 22, 2011
Received: August 23, 2011

Dear Mr. Barritt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known):

Device Name: Surgimap Spine

Indications for Use: The Surgimap Spine software assists healthcare professionals in viewing, storing, and measuring images as well as planning orthopedic surgeries. The device allows service providers to perform generic as well as spine related measurements of the images, to plan surgical procedures (osteotomies), and includes tools for measuring anatomical components for placement of surgical implants. Clinical judgment and experience are required to properly use the software.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _______ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Patel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111019